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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLDBERG, JEROME D

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/027,186

Applicant(s)

LEE, FRANCIS

Examiner

Jerome D Goldberg

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 6,9-13,16-21,24-26,28-36 and 39-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,14,15,22,23,27,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claims 6, 9-13, 16-21, 24-26, 28-36 and 39-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicants' elected the enhanced combination of CA4P and taxol with traverse in a future response. The restriction requirement is herein modified in that all the taxanes will be examined with the CA4P compound. The other enhanced combinations, which are classified in different subclasses, will support separate patents. Therefore, the restriction requirement as modified is herein made Final.

Claims are being examined as they read on the elected invention of the enhanced combination of taxanes and CA4P.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7, 8, 14, 15, 22, 23, 27, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Pettit patent of record taken with the Cahan et al. reference.

The instant application has an effective date of December 22, 2000 while the prior art patent has an effective date of October 1, 1996 and the prior art reference has an effective date of 1994. The Pettit patent teaches applicants' compound (wherein 1 is h see col. 1, line 55 to col. 2, line 15) for the "treatment of one or more neoplastic diseases. For example, ..., malignant melanoma, ... breast carcinoma, Ovarian carcinoma, ..., and the like" (col. 6, lines 2-7) in "humans" (col. 6, line 28). The Cahan et al. reference teaches that taxol "has shown clin. activity against several tumors, including ovarian and breast carcinoma and melanoma "(AB, lines 1-3). The above reference and patent do not teach the combination together. However, one skilled in this art would find ample motivation from the prior art supra to combine the well know anticancer agents together where the results obtained thereby are no more than the additive effects of the anticancer agents; particularly since the above prior art teaches the ingredient for treating the same cancer systems. See In re Sussman, 1943 C.D. 518. The data of record is noted but the showing in Figures 8-10 shown taxol alone to be better or equal to the elected combination. Moreover, Applicants state on page 40, lines 2-9 of the specification that "results indicate that administration of the two agents simultaneously was deleterious to the overall efficacy of the combination in this model

(Fig. 9). Allowing an interval of 3 hr between the administration of the two agents did not restore the overall efficacy of the combination, but overall efficacy was restored at an interval of 24 hours."

It is noted that the Pettit patent issued claim 2 is directed to treating "cells afflicted with a neoplastic disease" broadly. It is further noted that the instant elected combination is directed to well known anticancer agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Thursday from 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/LR
June 17, 2003

A handwritten signature in black ink, appearing to read 'J. D. Goldberg', with a large, stylized initial 'J' and a long, sweeping horizontal stroke.

JEROME D. GOLDBERG
PRIMARY EXAMINER